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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/786,937	01/22/1997	PHILIPPE BOUCHARD	098501-0235299	5859

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
02/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/786,937	BOUCHARD ET AL.	
	Examiner	Art Unit	
	CHRISTINA BORGEEST	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 14,38,39,42,44-51,56-63,65,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126.

Continuation of Disposition of Claims: Claims rejected are 14,38,39,42,44-51,56-63,65,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 November 2007 has been entered.

Formal Matters

The amendment filed 15 November 2007 is acknowledged. Claims 38 and 51 are currently amended. Claims 40, 41, 43, 52-55, 64, 66, 71, 76, 77, 81, 82, 85, 93, 101, 106, 109, 117, 120, 124 and 125 are canceled. Claims 38-39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are under examination.

Rejections Maintained/New Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. (cited in previous Office actions, mailed 13 September 2006 and 15 May 2007) as set forth at pages 4-6 of the Office action mailed 15 May 2007 is maintained for reasons of record and the following. It is noted that cancelled claims 52 and 53 were erroneously included in the previous rejection.

Applicants argue at p. 15, 1st paragraph that "as shown in Figures 1 and 2 on p. 789, daily doses of Cetrorelix were administered from day 7 until ovulation was induced on day 14 or 15 of the cycle.

This argument has been fully considered but is not found persuasive for the following reason. The claims recite "comprising" language, so although step (b) of claim 38 recites administration of a single or dual dosage regimen of 3 mg per dose, the claim is not limited to a single or dual dosage because of the comprising language. In other words, the use of "comprising" allows for additional steps in the method not specified in the claims.

Applicants argue at p. 15, 4th and 5th paragraphs and reiterated at p. 16, whole page, that Diedrich et al. do not describe a method comprising administering an LHRH antagonist in a single or dual dosage regimen of 3 mg per dose to prevent a premature LH surge with no effect on FSH levels as recited in claims 38 and 51 and cite Albano et al. as evidence of the method achieved without endogenous FSH suppression.

This argument has been fully considered but is not found persuasive for the following reasons. First, note that the language "comprising administering…" does not

limit the claims to a single or dual dosage regimen because comprising allows for the addition of steps not specified in the claims, namely additional administration of Cetrorelix. Second, note that claims 38 and 51 recite “but does not suppress ***endogenous*** FSH secretion, which is maintained at a natural level." (Emphasis added). The Applicants introduce evidence in the form of Albano et al., who teach that in this later study, unlike that of Diedrich et al., administration of Cetrorelix did not result in a decrease in FSH levels. Albano et al. are silent with respect to "endogenous FSH secretion" as recited in the claims, and in fact, at p. 2117, left column, Albano et al. state that “…our study did not reveal a decrease in FSH after the administration of the antagonist. This may be associated with the lower dose of antagonist used, or possibly to the influence of the exogenous FSH used." This statement strongly suggests that the absence of suppression might be do to exogenous FSH administered and not any difference in method claims from that of the prior art. In other words, the evidence cited does not distinguish between added and endogenous FSH levels—with respect to this, the art is silent. Finally, Felberbaum et al. (Human Reprod. 1999; 14: 207-21) teach at p. 210 that in response to a protocol administering 3, 1, 0.5 or 0.25 mg Cetrorelix/day, little suppression of FSH was observed "mainly due to the fact that ***exogenous*** FSH [emphasis added], which has a distinctly longer half-life in comparison to LH had been constantly administered during ovarian stimulation.” Because the claims encompass the method steps of Dietrich et al., and because the art cited by Applicants, as well as post-filing date art, do not provide sufficient evidence that the two methods can be distinguished, Applicants arguments are not persuasive.

Applicants' note at p. 16, end of the 1st full paragraph that Diedrich et al. is a named inventor of the instant application, but this information is not relevant to the rejection.

Claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Olivennes et al. (Human Reprod. 1995; 10: 1382-1386). Olivennes et al. teaches administering an exogenous gonadotropin to induce follicle growth (see p. 1383, left column, 3rd paragraph), and administering Cetrorelix (LHRH antagonist) to prevent a premature LH surge, ovulation occurs between day 9 and 20 of the menstruation cycle or within 6.5 days following administration of the LHRH antagonist (see p. 1383, Figure 1), wherein the Cetrorelix administered in a single or dual dosage regimen of 3 mg per dose beginning on menstruation cycle day 8 (see p. 1383, 4th paragraph) and wherein ovulation is induced by administering hCG (see p. 1383, left column, 5th paragraph). Olivennes et al. also teach that LH levels decrease, while FSH concentrations are not modified (see p. 1384, left column, 2nd and 3rd paragraphs). Thus the claims do not teach anything new over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 38-39, 42, 45-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, 126-141 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of copending Application No. 10/661,780 is maintained for reasons of record and the following.

Applicants' argue at p. 17, last paragraph that if the provisional rejection is the only remaining rejection, the Examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer (MPEP 804 I.B.1) in their response filed 11 November 2007. However, since the provisional rejection is not the only remaining rejection in the application, it must be maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest, whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646